

REMARKS

The Amendments

Independent claim 1 and the method of preparation claims are amended to incorporate the substance of claim 10 therein. Thus, the claims recite that the composition is provided in tablet or capsule form.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which may have been canceled by any of the above amendments.

The Rejections under 35 U.S.C. §103

The rejections of claims 1 and 6-15 under 35 U.S.C. §103, as being obvious over Ambuhl (US Pub. No. 2004/0198645) in view of Hauel or further in view of Gaviraghi (WO 00/27397) and Ohkouchi (US Pub. 2004/0180085), are respectfully traversed.

Applicants acknowledge the indication in the Advisory action that the PCT filing date printed on the Ambuhl reference is a typographical error and that it was filed on May 8, 2002. Thus, applicants' arguments made in the Reply filed March 30, 2011, are not applicable.

Ambuhl teaches providing novel galenical compositions for a poorly water-soluble drug, such as a cyclosporine. The Ambuhl invention is particularly directed to the difficulties encountered with putting cyclosporins in a galenical composition. The difficulties addressed are not merely the poor solubility; see page 1, para. 0002. The Ambuhl compositions contain the cyclosporin, a solid polymer and/or a surfactant and a carrier; see para. 0008. The surfactant can be, among many other choices, a polyoxamer. The carrier can be, among other choices, a water-soluble carrier such as mannitol. The Ambuhl compositions are solid and can be in the form of a tablet, capsule or powder.

Ambuhl does not disclose any composition containing telmisartan or any teaching at all regarding telmisartan. Further, Ambuhl provides no teaching or suggestion of using a basic agent, particularly NaOH, KOH, NaHCO₃, KHCO₃, Na₂CO₃, K₂CO₃, Na₂HPO₄, K₂HPO₄ or meglumine, in its compositions. To the contrary, Ambuhl is very specific and comprehensive about the possible components of its compositions. Ambuhl discusses many types of options for every possible component in its compositions. The fact that, despite this comprehensive discussion, it provides no hint to include a basic agent of the type recited in

the claims would suggest to one of ordinary skill in the art that such an agent should be avoided.

Hauel discloses compounds of its generic formula (I) (page 1) which encompasses telmisartan. Telmisartan is specifically identified, e.g., in claim 6, as pointed out in the Office action. Hauel also provides a disclosure regarding compositions of its compounds generally, see page 53 and specific Examples I-VII at pages 113-118. In these specific examples, the composition is provided in the form of ampoules, tablets, capsules, oral suspensions and suppositories. The composition examples are not of any specific active agent.

Hauel does not provide a general disclosure to include a basic agent component or a poloxamer component in its compositions. Examples IV and V contain lysine, which is a basic agent but is not NaOH, KOH, NaHCO₃, KHCO₃, Na₂CO₃, K₂CO₃, Na₂HPO₄, K₂HPO₄ or meglumine. Also Hauel discloses in Example II a composition which is a liquid composition in an ampoule which contains methyl glucamine (i.e., meglumine). Hauel does not disclose why the meglumine is added and provides no general discussion in its text which would indicate why meglumine would be added.

Applicants urge that the teaching in one example of Hauel to add meglumine to a liquid composition would not suggest to one of ordinary skill in the art to modify a solid, tablet or capsule, composition of Ambuhl to add meglumine thereto. One of ordinary skill in the art is not provided with any reason to add meglumine or another base to the solid tablet or capsule compositions of Ambuhl. Hauel only teaches to add the meglumine base to provide a liquid solution, which is not part of the Ambuhl invention (nor the claimed invention as currently amended). Further, the teachings in Ambuhl would direct one of ordinary skill in the art away from adding a base component. The teachings in Ambuhl are very comprehensive about what should be included in its compositions. It is taught in Ambuhl that these components provide what is necessary to provide a galenical composition for its poorly soluble active agent, cyclosporins. Despite the many possible components Ambuhl discusses as achieving this objective, it never discusses or gives any hint to add a basic agent, particularly not NaOH, KOH, NaHCO₃, KHCO₃, Na₂CO₃, K₂CO₃, Na₂HPO₄, K₂HPO₄ or meglumine.

Additionally, applicants urge that one of ordinary skill in the art would not have combined the teachings of Ambuhl and Hauel in the first place. Ambuhl is particularly

directed to providing compositions for cyclosporins. Ambuhl has some broader language about poorly soluble compounds but this is very vague and it would be clear to one of ordinary skill in the art that Ambuhl is only providing a solution to the problem of providing cyclosporins in a galenical form. One of ordinary skill in the art would not have a reasonable expectation that the Ambuhl compositions would also be effective for providing a suitable galenical composition where the cyclosporin active is substituted by telmisartan. The actives have different structures, properties and uses. The mere broad common property that both are poorly soluble would not give one of ordinary skill in the art a reasonable expectation that any composition form for a cyclosporin would also work for telmisartan.

The additional rejection of claim 13 in view of Gaviraghi and Ohkouchi is traversed for the same reasons as above. The additional references are not cited for and do not remedy the deficiencies of the Ambuhl and Huel references discussed above.

For all of the above reasons, applicants respectfully submit that the combined teachings of the cited references fail to render any of the instant claims obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,
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